SECTION 5: 510(k) SUMMARY

JAN 2 4 2013

Submitter:
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Date of preparation: 24 October 2012

Name of device: *Trade/Proprietary Name:* Reprocessed Steerable Introducer
Classification Name: Catheter introducer

Predicate Device	510(k) Title	Manufacturer
K081645	AGILIS NxT Steerable Introducer (Model G408324)	St. Jude Medical
K061363	AGILIS NxT Steerable Introducer	St. Jude Medical

Device Description:
The Reprocessed Steerable Introducer Set consists of a dilator, guidewire, and steerable sheath, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer is filtered with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. A handle equipped with a rotating collar to deflect the tip clockwise less than or equal to 90 degrees. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

Indications for Use:
The Reprocessed Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Technological Characteristics:
The design, materials, and intended use of Reprocessed Steerable Introducer are identical to the predicate devices. The mechanism of action of Reprocessed Steerable Introducer is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of Steerable Introducer includes removal of adherent visible soil and decontamination. Each

individual Introducer is tested for appropriate function of its components prior to packaging and labeling operations

Performance data:
Bench and laboratory testing was conducted to demonstrate performance of Reprocessed Steerable Introducer. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Steerable Introducer perform as originally intended.

Conclusion:
Stryker Sustainability Solutions concludes that the modified devices (Reprocessed Steerable Introducer) are substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 2 4 2013

Stryker Sustainability Solutions, Inc.
c/o Amanda Babcock
Regulatory Affairs Lead
1810 W Drake Dr
Tempe, Arizona 85283

Re: K123334
Trade Name: Reprocessed Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 24, 2012
Received: October 26, 2012

Dear Ms. Babcock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123334

Device Name: Reprocessed Steerable Introducer

Indications For Use: The Reprocessed Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123334